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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/163,778 | 09/30/1998 | ALLAN LEPINE | IAM498PA | 5876 |

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| EXAMINER | |
|---|---|
| SAYALA, CHHAYA D | |
| ART UNIT | PAPER NUMBER |
| 1761 | |

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/163,778 | LEPINE, ALLAN | |
| | Examiner | Art Unit | |
| | C. SAYALA | 1761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/29/05 has been entered.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 3-5, 7-9 and 11-12 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted Prior Art in view of Craig et al. (US Patent 5,795,602) and Lepine (US Patent 5,792,501).

The specification discloses that naturally occurring beagle milk contains various components, including 40.40% protein, 31.8% fat, 18.5% carbohydrate, and a casein/whey ratio of 70:30 (Specification, page 5, lines 21-26). The specification also admits that it is "generally accepted that milk from the lactating mother provides optimal nutrition to the suckling puppy. Accordingly, milk

replacers currently in use have been formulated with the intent of matching the nutrient composition of bitch milk." (Id., page 1, lines 8-11).

Naturally occurring canine milk contains all of the elements of instant claim 1. Even though applicant has added the limitation that the composition is artificially produced canine milk, it is noted that the both the milk and the substitute have the same utility and the same ingredients, and every composition is necessarily a combination of elements, and to that extent is artificially produced or synthesized. Furthermore, the limitation "the composition is an artificially produced canine milk substitute", adds little to the composition itself in order to distinguish it from the prior art because, again, the composition is the same and the utility is the same. The limitation is written in a product-by-process format and as such, it is the novelty of the instantly claimed product that need be established and not the way it was made. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976).

Given the known desired formulation of milk replacers to closely match the nutrient composition of canine milk, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a milk replacer with the composition of claim 1 to match the components of the natural beagle milk. See PTO-form 892 and the references applied herein that already establishes that to manufacture milk replacers that are similar or come close to the natural product was known in the art at the time the invention was made, and the knowledge to analyze and combine such ingredients to make a synthetic product was available at the time the invention was made.

The following claims are met as follows:

Instant claim 3 recites "about 38% protein". Natural beagle milk contains 40.40% protein (Specification, page 5, lines 21-26), which clearly anticipates a composition containing "about 38%" protein. In the alternative, it would have been obvious to formulate a canine milk replacer which contains about 38% protein, as it was known to formulate milk replacers to match the content of natural milk.

Instant claim 4 recites "about 28% fat". Natural beagle milk contains 31.8% fat (Specification, page 5, lines 21-26), which clearly anticipates a composition containing "about 28%" fat. In the alternative, it would have been obvious to formulate a canine milk replacer which contains about 28% fat, as it is known to formulate milk replacers to match the content of natural milk.

Instant claim 5 recites "about 19% carbohydrates". Natural beagle milk contains 18.5% carbohydrates (Specification, page 5, lines 21-26), which clearly anticipates a composition containing "about 19%" carbohydrates. In the alternative, it would have been obvious to formulate a canine milk replacer which contains about 19% carbohydrates, as it was known to formulate milk replacers to match the content of natural milk.

Instant claim 7 recites 15-19% palmitic acid, about 5-9% stearic acid, about 34-38% oleic acid, about 17-21% linoleic acid, 1-4% alpha-linoleic acid, about 0.5-2.0% arachidonic acid, about 0.2-1% docosahexaenic acid, about 2-5% Omega-3 fatty acids, about 18-22% Omega-6 fatty acids, and from about 1-4% trans fatty acids.

Instant claim 8 recites about 6-10% arginine, 4-8% histidine, 8-12% isoleucine, 16-20% leucine, about 13-17% lysine, about 2-7% methionine, about 6-10% phenylalanine, about 8-12% threonine, about 1-4% tryptophan, about 9-13% valine, about 2-5% cystine, and about 2-6% tyrosine, based on the total weight of amino acids.

Instant claim 9 recites about 4-8% by weight lactose.

Instant claim 11 recites about 27-37% by weight fatty acids.

Instant claim 12 recites from about 15 to 15% by weight essential amino acids.

Although the claimed ranges are not specifically exemplified or analyzed for in the Admitted Prior Art beagle milk, the compositions of the claimed milk replacer and the prior art beagle milk are so close (and stated to be modeled upon natural beagle milk) that they are reasonably expected to behave in the same or similar manner. Compare Titanium Metals Corp. v. Banner, 778 F.2d 775, 783, 227 USPQ 773, 779 (Fed. Cir. 1985).

Where general conditions of the appealed claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation, and applicant has the burden of proving any criticality. In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-19 (CCPA 1980). In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Applicant has not done so with the claimed compositions vis-à-vis natural beagle milk.

Note that the above discussion does not show a teaching of the addition of pyridoxine hydrochloride, which is vitamin B6. Craig et al. teach a milk replacer

for animals which includes vitamins and minerals. The vitamins include pyridoxine hydrochloride. See col. 5, lines 45-49. Lepine also to a milk replacer composition for young animals, includes vitamins and minerals that comprise pyridoxine hydrochloride (col. 7, line 64). It is so well known that vitamins and minerals, including vitamin B6 are advantageous to the growth and maintenance of young animals, in fact *any* animal, that the inclusion of vitamin B6 would have been obvious, if not a foregone conclusion, to the artisan, barring any evidence to the contrary.

2. Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art in view of Craig et al. (US Patent 5,795,602) and Lepine (US Patent 5,792,501) and further in view of Gil et al. (US Patent 5709888).

Instant claim 6 recites that the source of fat is corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

Instant claim 14 recites that the composition contains about 35-45% protein, about 25-35% fat and from about 10-25% carbohydrates, and the fat is corn oil canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

The admitted prior art and the art showing vitamin B6 is as discussed above. It does not disclose that the fat was obtained from the sources claimed herein. Gil teaches a preferred source of fat for a human-milk replacer includes oil, such as corn oil (see col. 10, line 64). Gil also experimentally teaches

feeding weanling rats (see col. 24, line 59 etc.) the composition from its example 13. Example 13 and example 4a contain the same fat mixtures, and example 4a is said to contain arachidonic acid and docosahexaenoic acid that have a beneficial effect on the rats (see col. 17, lines 40-58).

Consequently, it would have been obvious to utilize corn oil, arachidonic acid and docosahexaenoic acid as a fat source in the instantly claimed canine milk replacer of claims 6 and 14 to obtain the beneficial effects found in humans and rats with the reasonable expectation that such benefits extend to all animals.

3. Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art in view of Craing et al. and Lepine, with or without Fujimori (US Patent 5294458).

Claim 10 recites that the composition contains about 0.50% by weight fructooligosaccharide.

Claim 13 recites that the composition contains about 35-45% protein, about 25-35% fat and from about 10-25% carbohydrates, further containing about 4-8% by weight lactose and 0.50% by weight fructooligosaccharide (FOS).

The Admitted Prior Art and Craig te al and Lepine are as discussed above. The Admitted Prior Art (specification, page 7, lines 16-22) further states that 0.50% FOS is known to improve the intestinal health of "many animals". Accordingly, it would have been obvious to incorporate FOS into the claimed composition. Lepine also teaches that the addition of FOS (0.50%) in milk replacers help enhance the establishment of favorable intestinal microflora.

Alternatively, Fujimori teaches that fructooligosaccharides known to be in pet foods to reduce objectionable odors in pet wastes (see, e.g. Fujimori, col. 2, lines 45 etc.). The lactosucrose is utilized in an amount of 0.25 parts by weight (col. 6, lines 25-26). Accordingly, it would have been obvious to use the fructooligosaccharide in the canine milk replacer, correspondingly to obtain the known benefits.

4. Claims 1, 3-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (DE 3512705) in view of admitted Prior Art, GB 2030439 and Smirnova et al. (Voprosy Pitaniya, No. 5, pp. 36-39, 1981).

Meyer teaches a milk substitute especially for dogs that contains a fat content of more than 25%, protein content of more than 30%, a carbohydrate content of less than 25%. See pages 3-4 of the translation. The patent teaches an albumin-globulin to casein ratio (page 4, third paragraph) but does not disclose the ratio of casein to whey as claimed herein. However, the analysis of the milk of various animals was already known in the art at the time the invention was made and it was also known that of all the milk proteins, casein is much more prevalent in milk than whey proteins. Since the albumin-globulin to casein ratios are given in Meyer, based on such information to formulate and optimize amounts of casein to whey, with the knowledge that casein is more prevalent than whey would have been obvious.

The GB patent teaches a milk substitute that uses 17% casein and 6% whey (see example 1), whereas the abstract of Smirnova et al. teaches a rat milk substitute which contains 73% casein and 27% whey.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the milk substitute to closely match the natural product as given in the admitted prior art, this being the optimal diet for animals and providing motivation to do so. The secondary references establish that at the time the invention was made it was not unknown to make a milk substitute with a casein to whey ratio in the claimed range. Every one of the above references teaches the addition of vitamins and minerals, and therefore, without more, it would have been obvious to one of ordinary skill in the art that such an addition would have included vitamin B6 for its well established function and benefit.

***Response to Arguments***

Applicant's arguments filed 8/29/05 have been fully considered but they are not persuasive.

At page 7 of his arguments, applicant's conclusion that "One reading Fujimori would not desire to use Applicant's fructooligosaccharide in a pet dog food since this reference considers this to be inferior to the lactosucrose disclosed in Fujimori." This position is incomprehensible for several reasons. For instance, the patent does not make such a statement anywhere in the patent (i.e. even by comparatives). Second, the reference teaches that lactosucrose

has a higher selectivity for bifidobacteria, while it is known that this is only one of the intestinal microflora. Additionally, Lepine reinforces the Fujimori teaching by stating that intestinal microflora is enhanced by FOS.

With regard to the Meyer reference, applicant's remarks have been carefully considered, but the fact remains that when one of ordinary skill in the art knows the formulation of the milk of any animal, to replicate it as closely as possible knowing that such a replication would provide the best possible nutrients to the animal, would be all the motivation that is required to optimize the proteins, whey and casein, to the same amounts as in natural dog milk. Note, too that this reference was used in combination with other references, the Smirnova et al. reference being one of them, which contrary to applicant's position that it does not exhibit a specific casein to whey ratio, shows at page 3, casein to be 73% and whey to be 23% is a substitute rat's milk meant to be a model for milk replacer for young animals. It is well established that a reasonable expectation of success, not absolute predictability is necessary for conclusion of obviousness, In re Longi, 225 USPQ 545, In re Morston, 1961 C.D. 330, In re Clinton, 188 USPQ 365,In re O'Farrell, 7 USPQ2d 1673, 1681 (Fed Cir 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. SAYALA whose telephone number is 571-272-1405.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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